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| 10/052,771 | 01/23/2002 | John A. Schillinger | N1206-373 | 7104 |

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| EXAMINER |
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PARA, ANNETTE H

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| ART UNIT | PAPER NUMBER |
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1661

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03/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/052,771

Applicant(s)

SCHILLINGER ET AL.

Examiner

ANNETTE H. PARA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/31/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-10, 25, 33, 35, 39, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 25, 33, 35, 39, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/31/2007
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Status of the claims

Claims 1, 2, 4-10 are rejected. Claims 3, 11-24, 26-32, 34, 36-38, 40, 41, and 44-49 are cancelled. Claims 25, 33, 35, 39, 42 and 43 are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-10, and 13 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Rhodes (U.S. Patent No. 5,710,368) in view of Russell et al. (EPO 0430511A1) and in view of Botterman et al. (Herbic. Resist. Weeds Crops 1991).

The claims are drawn to soybean plants and seeds comprising genes conferring resistance to glyphosate and glufosinate herbicides, wherein the plant comprises a commercially acceptable grain yield.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Rhodes teaches soybean seeds and plants that have resistance to glyphosate (Roundup™) and contain the Als gene for sulfonylurea tolerance (column 5, lines 20-22) and have shown commercially acceptable grain yield (column 6, table 1, column 4, 5, and 6). Rhodes also teaches methods for producing a soybean plant by crossing a first soybean plant with a second one (column 6, lines 17-21). Rhodes does not teach soybean plants that are resistant to glufosinate.

Botterman et al. teach soybean plant resistant to glufosinate, the resistant or tolerant phenotype has shown no yield penalties, which is commercially acceptable grain yield (p. 359, lines 1-4). Botterman et al. also teach the transfer of the resistance trait to various cultivars (p.360, last paragraph, p.36, first paragraph). Botterman et al. do not teach soybean plants that are resistant to glyphosate.

Russell et al. teach a method of inserting DNA into plant cells (p.2, lines 30-55). Russell et al. teach soybean plants with an inheritable trait of resistance to glutamine synthetase inhibitors (whole document). Russell et al. do not teach soybean plants that are resistant to glyphosate.

At the time of Applicant's invention the method for producing a soybean plant that have resistance to two herbicides was well know in the prior art. Botterman et al teach introducing resistance gene linked to other genes conferring agronomically useful traits (e.g. commercially acceptable grain yield) via transformation (p.360, last paragraph), and then in a plant-breeding program transferring the traits to various cultivars. Russel et al. teach a technology involving the physical delivery of DNA into plant cells (p.2, lines 30-55).

At the time of Applicant's invention it would have been obvious to one of the ordinary skill in the art to modify the soybean plant as taught by Rhodes by crossing it with Botterman et al. soybean plant as taught by Botterman et al. (p.360, end of second paragraph and p.361, first paragraph) or by using the method of delivery of DNA into plant cells taught by Russell et al. (p.2, lines 30-55).

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As the herbicide-resistance genes are used in crop plants so they will be resistant when herbicides are applied (see Russell page 2, lines 47-49), one ordinary skill in the art would have been motivated to develop soybean plants comprising genes conferring resistance to glyphosate and glufosinate to take full advantage of the synergetic effects of using multiple herbicides on crop fields knowing that Rhodes had soybean plant resistant to two herbicides, which have shown commercially grain yield.

Thus the claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

Byrum's declaration filed on October 16, 2006 has been fully considered but they are not persuasive. Byrum states that at the time of the invention a soybean variety had not been developed having more than one herbicide resistance trait.

This is not found persuasive. Rhodes teaches soybean seeds and plants that have resistance to glyphosate (Roundup™) and contain the Als gene for sulfonyleurea tolerance (column 2, lines 20-22).

At the time of the claimed invention one of skill in the art would have been able to perform gene stacking and obtain soybean plants containing transgenes conferring tolerance to both glyphosate and glufosinate.

Byrum then states that any assertions that glyphosate and glufosinate herbicide resistance transgene could be successfully expressed in a single variety while maintaining a commercially acceptable soybean grain yield would therefore be speculation.

This is not found persuasive. The statement of Rhodes that the cultivar has shown uniformity and stability for the following traits: seed yield, lodging resistance, emergence..etc. Furthermore, Botterman et al. state

“The strategy followed here to engineer plants resistant against a broad spectrum herbicide clearly illustrate the advantage for using bacterial detoxifying enzymes. This system is independent from the plant species, is highly effective and has no effect on crop performance (p.361, 2nd paragraph).

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Applicant seems to be implying that expression of more than one transgene in a plant has never been done before. At the time the instant application was filed Rhodes and Botterman were teaching plant expressing more than one transgene. Plants are routinely transformed with constructs that express both selectable marker and the gene of interest. Expressing two genes in plants is routine, and one of skill in the art would not expect that both could not be expressed.

In the Applicant's response received on July 19, 2007, Applicant argues that Rhodes cannot be used as Prior Art because being owned by Asgrow Seed Company as the present case (p. 4 of applicant's response).

This is not found persuasive because Applicant does not show that the common ownership exists at the time the present invention was made. Applicant fails to provide a statement that the present application and Rhodes reference were owned by, or subject to an obligation of assignment to Asgrow Seed Company at the time the invention was made in a conspicuous manner, and therefore is not disqualified as prior art under 35 U.S.C. 103(a).

Applicant must file the required evidence in order to properly disqualify the Rhodes' reference under 35 U.S.C. 103(c). See MPEP § 706.02(1). In addition, applicant may overcome the applied art either by a showing under 37 CFR I. 132 that the invention disclosed therein was derived from the inventor of this application, and is therefore not the invention "by another", or by antedating the applied art under 37 CFR 1.131. The Examiner notes that the instant application contains no inventor(s) in common with the '368 patent.

Applicant argues that because the Restriction Requirement states that "the invention of Groups I-XXVI are each capable of being separately made, independently used and the patentability of one would not render the other obvious or unpatentable, therefore the currently invention is not rendered obvious or unpatentable by any plants and seeds that are resistant to at least two herbicides or soybean plants and seeds resistant to at least two herbicides or soybean plants and seeds resistant to ALS inhibitor and glufosinate herbicides. Therefore the Office cannot now assert the opposite (pp.5-6 Applicant's response).

This is not found persuasive because a restriction requirement is not an admission by the Office of patentability.

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Furthermore, Applicant argues that Botterman et al. do not teach transgenic glufosinate-tolerant soybean plants but teach other species such as tobacco, sugar beet and alfalfa resistant to glufosinate. Applicant then argues that because of the absence of field tests conducted on soybean with glufosinate resistance, the result from producing the soybean plant with this trait is speculative and unpredictable. (p. 6 Applicant's response)

Examiner admits to an error in the facts and extends her apologies; still, the Applicant's argument is not found persuasive because Botterman et al. teach a soybean plant resistant to Glyphosate tested in field trials (p.358 paragraph 5). Botterman et al also teach field trials with glufosinate resistant tobacco, sugar beet, tomato, potato, poplar and alfalfa. In most cases herbicide resistance was observed and no yield penalties were observed (p. 358-359). Furthermore, Russell et al. teach a soybean plant resistant to glutamine synthetase inhibitors using the Bar gene method as Botterman et al.(whole document). Every limitation of claims 1,2 and 4-10 are taught in the prior arts and at the time of the present invention it would have been obvious to combine the teaching of the prior arts for the reason stated in the previous office action mailed on January 19, 2007.

Finally, Applicant argue that one skill in the art would not have reasonably predicted as of the filing date that a plant could be obtained comprising transgenes conferring tolerance to glyphosate and glufosinate and also having commercially significant yield. Applicant cites Byrum's declaration, which states that no soybean variety was ever developed prior to the invention having more than one herbicide resistance transgene combine in a single soybean plant.

This is not found persuasive because Botterman et al. teach plants resistant to glufosinate, the trait being inherited as a dominant Mendelian trait. Knowing that it would have been obvious to cross a transgenic soybean plant resistant to both Glyphosate and Glufosinate with one with a high yield production trait as taught by Rhodes.

Rhodes teaches soybean seeds and plants that have resistance to glyphosate (Roundup TM) and contain the Als gene for sulfonylurea tolerance (column 2, lines 20-22). Hence, at the time of the present invention a

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soybean plant variety had been developed having more than one herbicide resistance transgene combine in a single soybean plant.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H Para whose telephone number is (571) 272-0982. The examiner can normally be reached Monday through Thursday from 5:30 a.m. to 4:00 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where the application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either

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Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about PAIR system, see <http://pair-direct.uspto.gov> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Annette H Para/